



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR - 6 2004

Mr. Mark W. Rollison
President
Kendy USA LLC
704 Juniper Drive
Palantine, Illinois 60074

Dear Mr. Rollison:

This is in response to your letter of January 12, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Kendy USA LLC is making the following claims for the product BIOPLUS+:

“Restores intestinal flora after antibiotic treatment and intestinal infections”
“Prevent constipation...diarrhea...”

These statements suggest that this product is intended to treat, prevent, or mitigate diseases. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000), FDA stated that certain claims about constipation (see 65 FR 1000 at 1015; comment 38) and the treatment of the consequences of antibiotic therapy (see 65 FR 1000 at 1029; comment 81) were disease claims. The same principles that apply to claims about constipation would also apply to claims about diarrhea.

The product also uses the claim “Help maintain normal blood cholesterol levels.” In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product does not establish that the claim is about a blood cholesterol level that is already within normal limits and, therefore, implies that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease.

975-0163

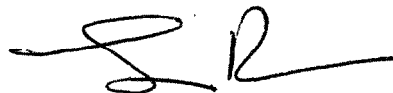
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Page 2 - Mr. Mark W. Rollinson

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJ Walker', written in a cursive style.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Chicago District Office, Office of Compliance, HFR-MW140

704 Juniper Drive,
Palatine, IL 60074
T/F. 847 776 0611

Kendy USA LLC

12 January, 2004

Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

FEB 18 2004

**RE: Kendy USA LLC – Notification pursuant to Section 6 of DSHEA
and 21 CFR 101.23**

To whom it may concern:

As required under 21 C.F.R. ss 101.93, Kendy USA LLC (Kendy) is enclosing one original and two copies of this notification and two labels for it's new dietary supplement BIOPLUS+, which will be available in both capsule and lozenge formats. The BIOPLUS+ labels contain structure/function statements allowable under 21 USA 403(r) along with accompanying qualifying statements as dictated by the regulations.

- 1) The dietary supplement is BIOPLUS+.
- 2) BIOPLUS+ is made in Bulgaria and Distributed by Kendy USA LLC, 704 Juniper Drive, Palatine, IL 60074.
- 3) The texts of the statements are included on the attached labels.
- 4) The new dietary ingredient contained in the BIOPLUS+ products is *Lactobacillus bulgaricus*.

This notification is complete and accurate and Kendy can substantiate that its statements are truthful and not misleading.

Sincerely,

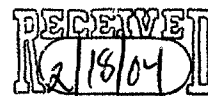
Mark W. Rollinson

Mark W. Rollinson
President

Date: 12 January 2004

87577

Kendy USA LLC
"Your partner is business"



704 Juniper Drive,
Palatine, IL 60074
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12 January, 2004

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Sincerely,

Mark W. Rollinson
President

Date: 12 January 2004

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This notification is complete and accurate and Kendy can substantiate that its statements are truthful and not misleading.

Sincerely,



Mark W. Rollinson
President

Date: 12 January 2004



Each tablet (1.6g) contains minimum 80,000,000 viable lactic acid probiotic bacteria at time of expiration.

Clinical studies show that the regular use of probiotics may:

- Support your body's immune system by maintaining levels of immunoglobulin A, M & G.*
- Promote correct digestion and absorption of food nutrients.*
- Help maintain normal blood cholesterol levels.*
- Maintains normal gastro-intestinal micro flora.*
- Restores intestinal flora after antibiotic treatment and intestinal infections.*

- Help fight stress related conditions.*
- Prevent constipation, bloating, diarrhea & flatulence.*
- Overcome skin problems.*

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

*The Bulgarian farmers' longevity and good health were due to the consumption of fermented dairy products containing Lactobacillus Bulgaricus.**

I. Mechnikov, Nobel Prize winner in Medicine - 1908

First identified in Bulgaria in 1905, probiotics are defined by most scientists as "live microbial food additives which have beneficial effect on man by improving the internal microbial balance".*

Composition:
Low-lactose dry milk Biotim LBS, Lactobacillus Bulgaricus, Streptococcus Thermophilus, pectin, oligopeptides, dipeptides & free amino acids, vitamins, trace elements, citric acid, dextrose.

SUPPLEMENT FACTS

Serving size: 1.6g (1.6g)		Serving size: 1.6g (1.6g)	
Amount		Amount	
%Daily		%Daily	
per serving		per serving	
value		value	
Calories		5 kcal	
Total Carbohydrates		1g	
		<1%	

Viable probiotic cells: 80,000,000** †

RECOMMENDED DAILY DOSAGE:
2-4 tablets (double the dosage if recovering from illness or after a course of antibiotics). Suitable for adults or children over the age of 3.

No side effects observed in clinical tests.



All natural
biostimulator

Sugar free - Natural caramel taste



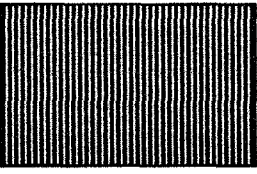
All natural
biostimulator

The "good bacteria" to optimize your body's immune and digestive systems.*

Patented formulation contains 3 unique strains of Lactobacillus Bulgaricus from Bulgaria, where probiotics were first discovered.

Dietary supplement

90 Chewable tablets



Best before:
Batch No:

The strains of Lactobacillus Bulgaricus, from the collection at the National Bank for Micro-organisms and Cell Cultures of Bulgaria.

Store in a cool, dry place below 66°F, preferably in the refrigerator.

Made in Bulgaria. Distributed by Kendy USA LLC, Palatine, IL.

www.kendyusa.com

NATURAL PRODUCT
Does not contain genetically modified substances.

BIOPLUS+™
PRE/PROBIOTIC

All natural
biostimulator

Each capsule (400mg) contains
minimum 45,000,000,000 viable
probiotic bacteria at time of
expiration.

Clinical studies show that the regular use of probiotics may:

- Support your body's immune system by maintaining levels of immunoglobulin A, M & G.*
- Promote correct digestion and absorption of food nutrients.*
- Help maintain normal blood cholesterol levels.*
- Maintain normal gastro-intestinal micro flora.*
- Restore intestinal flora after antibiotic treatment and intestinal infection.*
- Help fight stress related conditions.*
- Prevent constipation, bloating, diarrhea & flatulence.*
- Overcome skin problems.*

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

The Bulgarian farmers' longevity and good health were due to the consumption of fermented dairy products containing *Lactobacillus bulgaricus*.[†]

I. Mechnikov, Nobel Prize winner in Medicine - 1908

First identified in Bulgaria in 1905, probiotics are defined by most scientists as "live microbial food additives which have beneficial effect on man by improving the internal microbial balance".*

Composition:
Lactobacillus acidophilus, Bifidobacterium
Streptococcus thermophilus, proteins, inulin,
glucose, galactose, calcium, potassium,
phosphorus

BIOPLUS+ is clinically tested.

SUPPLEMENT FACTS

Serving size: 1 capsule (400mg)
Servings per container: 90

Amount	%Daily	per serving	value
Calories	1.5 kcal		
Total Carbohydrates	120mg		<0.2%
Viable probiotic cells:	45,000,000,000**		†
Lactobacillus acidophilus			
Streptococcus thermophilus			
Lactobacillus bulgaricus			
Bifidobacterium bifidum			

** At time of expiration
† Daily value not established

RECOMMENDED DAILY DOSAGE:
2-4 capsules (double the dosage if recovering from illness or after a course of antibiotics).
Suitable for adults or children over the age of 3.
No side effects observed in clinical tests.

BIOPLUS+™
PRE/PROBIOTIC

All natural
biostimulator

BIOPLUS+™
PRE/PROBIOTIC

All natural
biostimulator

Acidophilus/Bifidum/Bulgaricus/
thermophilus/inulin blend.

The "good bacteria" to
optimize your body's
immune and digestive
systems.*

Patented symbiotic blend
includes acidophilus, bifidum,
thermophilus & 3 unique
strains of Lactobacillus
bulgaricus from Bulgaria,
where probiotics were first
discovered.

Dietary supplement

90 Capsules

The strains of Lactobacillus acidophilus,
Lactobacillus bulgaricus, Bifidobacterium
bifidum and Streptococcus thermophilus,
from the collection of Lactina Ltd., are
registered at the National Bank for Micro-
organisms and Cell Cultures of Bulgaria.

Store in a cool, dry place below
68°F, preferably in the refrigerator.

Made in Bulgaria. Distributed by
Kendy USA LLC, Palestine, IL.

www.kendyusa.com

Best before:
Batch No:

NATURAL PRODUCT

Does not contain genetically modified
substances.

